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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,210	10/16/2001	Shian-Jiun Shih	A2922AUS	2753
5487	7590	06/13/2006	EXAMINER	
ROSS J. OEHLER SANOFI-AVENTSI U.S. LLC 1041 ROUTE 202-206 MAIL CODE: D303A BRIDGEWATER, NJ 08807			EPPS FORD, JANET L	
			ART UNIT	PAPER NUMBER
			1633	
DATE MAILED: 06/13/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/763,210

Applicant(s)

SHIH ET AL.

Examiner

Janet L. Epps-Ford

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-- The MAILING DATE of this communication appears on the certificate with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-5, 7-13, 18, 22-24, 26, 27 and 34-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-5, 7-13, 18, 22-24, 26-27, and 34-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Amendment

2. The rejection of claims 1, 3-5, 7-13, 18, 22-24, 26-31, and 34 under 35 U.S.C. 112, second paragraph, is withdrawn in response to Applicant's amendment.

New grounds of Rejection

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 3-5, 7-13, 18, 22-24, 26-27, and 34-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (New Matter).

Claim 34, and those claims dependent therefrom, claims 3-5, 7-13, 18, 22-24, 26-27, and 35-38, recite the following phrase: "stored at a temperature greater than about 4°C for at least about 3 months." However, there is no clear support for these open-ended ranges wherein applicants have support for storage temperatures that encompass all temperatures above 4°C, other than +20°C, and for all periods of time beyond 3 months, other than a maximum of 8.5 months to 1 year, wherein applicants

were able to enhance the titer of or preserve recombinant adenovirus vectors or particles. Applicant's amendment is considered new matter since the specification as filed does not provide adequate support for the full scope of the newly added limitations to the claims.

Response to Arguments

Claim Rejections - 35 USC § 103

5. Claims 7-13, 22-24, 26, and 34 remain rejected and new claims 35-38 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Crespo in view of Engler et al. (US 2003/021 1598); and claims 3-5, 7-13, 18, 22-24, and 26-27 remain rejected and claims 34-38 are rejected under 35 USC 103(a) as being unpatentable over Crespo in view of Engler et al. (US 2003/021 1598), and further in view of Rolland et al. and Sene, for the reasons of record.

6. Applicant's arguments filed 3-24-06 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that neither Crespo nor Engler et al. disclose the step of storing said recombinant adenovirus vectors or particles at a temperature greater than about 4°C. Moreover, Applicants argue that the disclosure of Crespo et al. that teaches temperatures of about 37°C, represent *thawing* conditions, and does not represent *storage* conditions of greater than about 4°C, as recited in the instant claims. Contrary to Applicant's assertions, the specification as filed, at page 34, lines 3-7, recites:

This Example summarizes the efficiency of a formulation comprising 10mM Tris-HCl + 5% HSA + 5% sucrose + 150mM NaCl + 2mM MgCl₂, pH 8.4 (Formulation 19) to preserve adenoviral vectors at four storage temperatures for 0 (2 days), 1.5, 3.5, and 8.5 months. This study was designed to determine optimal formulation of an adenovirus vector to achieve at least one (1) year stability when stored frozen at -20°C, or as a liquid at +4°C or +20°C storage temperatures.

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Specifically, it states that conditions that are greater than 4°C (i.e. +4°C) or +20°C, represent wherein the optimal formulation is in a liquid form, i.e. in a *thawed* form. Therefore, the teachings of Crespo et al., which encompasses, temperatures that fall within the range of **greater** than about 4°C (wherein there is no upper limit), actually meet the limitations of the claimed invention.

Moreover, Applicants suggest evidence of unexpected results as evidence of the non-obviousness of the claimed invention, however there is no support as stated above, in the specification as filed, wherein Applicants have demonstrated unexpected results for compositions useful for preserving adenovirus at **any** temperature above 4°C, and for **any** period of time.

Absent evidence to the contrary, one of ordinary skill in the art would have been motivated and would have had a reasonable expectation of success in employing the Tris-HCl/NaCl/ MgCl₂/HSA based solution (produced by the combination of Crespo and Engler et al.) in preserving and storing adenoviral vectors because each of the ingredients employed in the solution is expected to help stabilize and/or enhance the intended function of the adenoviral vectors, as taught by the combination of the references as a whole.

Conclusion

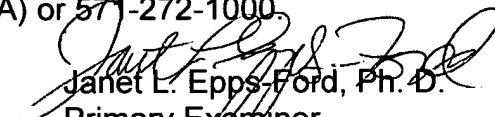
7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Janet L. Epps-Ford, Ph. D.
Primary Examiner
Art Unit 1633

JLE